MINUTES FROM THE EPA/SCIENCE ADVISORY BOARD Arsenic Rule Benefits Review Panel

Telephone Conference Meeting
August 14, 2001

PURPOSE: The Arsenic Rule Benefits Review Panel met via teleconference to discuss the Panel's draft report on its review of EPA's Economic Analysis supporting the National Primary Drinking Water Standard for Arsenic (see <u>Attachment A</u>). The meeting was announced in the Federal Register at FR Vol. 66, No. 145, Page 39163 (July 27, 2001) (see <u>Attachment B</u>). An agenda is included as <u>Attachment C</u>.

LOCATION: The meeting was coordinated from Room 6013, Ariel Rios Building, US EPA, 1200 Pennsylvania Ave., NW, Washington, DC.

PARTICIPANTS: The following participated in this meeting: Drs. Maureen Cropper, Richard Bull, A. Myrick Freeman, Michael Hanemann, Dale Hattis, Irva Hertz-Picciotto, and V. Kerry Smith. A committee roster is included as <u>Attachment D</u>. EPA Staff and persons from the public who participated in or observed the meeting are indicated on the log sheets (<u>Attachment E</u>).

MEETING SUMMARY: A summary of the Panel's activities follows.

1. Welcome and Introductory Remarks; Dr. Maureen Cropper, Chair, (8:30 am)

Members and public observers were logged into the call and Dr. Cropper called the meeting to order and welcomed the participants. She noted the purpose of the meeting. A disclosure process was not needed because of the recent conduct of the same at the July 19-20, 2001 meeting on the same subject.

2. Public Comment Period.

At the request of Mr. Miller, DFO, the Chair agreed to a revision of the agenda to move the public comment period to accommodate two members of the public who had requested (late) time on the agenda within the last 24 hours.

a. <u>Dr. Gunther Craun, for City of Albuquerque, NM.(10:13-10:16 am)</u>

Dr. Craun presented comments for the City of Albuquerque, NM (see Attachment F). The city had also submitted written comments on July 30, 2001 at the invitation of the Administrator in the Panel's July 19-20, 2001 meeting. He addressed the need: 1) for a serious attempt to quantify the uncertainties in the benefits analysis; 2) to consider causality in quantifying health risks; 3) to consider unintended consequences of the new rule (e.g., transportation accidents, waste disposal); and 4) to develop the cost and benefits analysis on a water system-specific basis.

b. Mr. Wesley Warren, for the Natural Resources Defense Council

On August 13, 2001, Mr. Warren had requested time early in the meeting to make a public comment. Three separate calls were made for Mr. Warren during the meeting with no response.

3. Discussion of Charge Question 1: How should **latency** be addressed in the benefits estimates when existing literature does not provide specific quantitative estimates of latency periods associated with exposure to arsenic in drinking water?

Dr. Cropper stated that she had received all but one of the email responses from Panelists on the draft report. The missing comment was that of Dr. Hanemann which had not been transferred to her by her. The comments that follow are with reference to the draft comments contained in the Panel's August 9, 2001 Panel Discussion Draft report.

The following comments and questions were raised in regard to Charge Question 1:

- a. Dr. Hattis would like to stress that latency estimates can be based upon multi-stage models and he offered to draft a few simple paragraphs explaining what could be done in this regard. He noted that the underlying data for the Morales (2000) paper has some information on outcomes after a period of greatly diminished exposure. He noted some doubt that NRC would address these issues.
- b. Dr. Cropper asked to what extent Dr. Hattis' approach is considered to be widely accepted.
- c. Dr. Bull noted that the latency assessment should be done using the same approach for as that used in estimating risk. He believes that the NRC report will cover this and that the Panel report needs to acknowledge their role in the overall arsenic reassessment. The Panel approach should be suggested as an example of what could be done, not what must be done. Noting that lifetime risk models do not look at the cessation lag would not step on NRC toes.
- d. The term cessation lag needs to be explained relative to latency in the letter to the Administrator.
- e. Dr. Smith noted 3 issues from the discussion:
 - i. The need for consistent modeling approaches for both potency and latency assessments
 - ii. Transfer from available empirical information to U.S. experience
 - iii. The issue of latency vs. cessation lag

He wondered if our advice infringed on the NRC charge and noted the need to tell EPA to give appropriate attention to how NRC addresses these issues. Specifying a latency method is outside our charge.

Define the "function of g" after equation 1 on page 4.

- f. Dr. Hertz-Picciotto noted that Brown and Chen and Hazleton contain analyses that indicate arsenic to be a fairly late stage carcinogen.
- g. The latency description sounds a bit like there are firm data available. This may be too strong of language.
- **4. Discussion of Charge Question 2**: How should **health endpoints (other than bladder and lung cancer)** be addressed in the analysis, when [existing] literature does not provide specific quantification, to ensure appropriate consideration by decision makers and the public?

The following comments and questions were raised in regard to Charge Question 2:

- a. Dr. Bull stated that we imply implementing new risk assessment approaches that will project the number of cases of various effects at alternative MCLs. EPA will not likely be able to overturn existing assessment policy and develop new ones in the time available for completing the arsenic rule. It may be enough if they update their existing work by arraying LED_{01} 's or ED_{01} 's to show how the nonquantified effects compare to those quantified. Exposure levels are the relevant point especially at low doses. Quantification is not the same as extrapolation.
- b. Dr. Freeman stated that we are to provide advice on how to do an adequate benefits analysis. The current approach does not provide anything to do benefits analysis upon.
- c. Dr. Hertz-Picciotto noted that EPA had already done many non-traditional things in the arsenic rule and that more might be called for because of the need for quantitative information to base benefits estimates upon. We should not require firmly established causality relationships to suggest what should be quantified, rather a significant body of evidence should be sufficient.
- d. Dr. Hattis noted that his suggested approach does provide some basis that also takes into account uncertainty. At least descriptions of what the data say about nonquantified effects in relation to those already quantified is needed.
- e. Dr. Smith summarized by noting three points had been made:
 - i. Risk levels permit benefits quantification given the existence of some peer reviewed way to assign willingness to pay points.
 - ii. Dr. Hertz-Picciotto says it is possible to quantify more health effects from EPA's list.
 - iii. It may be desirable to use another organizing framework that falls between a simple list and a fully quantified risk profile.
- f. In regard to a question about whether the Hattis approach would be taken as an appropriate method, Dr. Hattis noted that we will not be able to get all the nonquantified effects to the same point of acceptability as exists with cancer risk assessment, but it would at least give readers of EPA's regulatory support documentation a starting point to consider relative burdens. Further, we should also state that many of the effects are unlikely at low doses.
- g. Dr. Cropper summed up by saying that:
 - i. In an ideal case we would quantify effects on the basis of strong dose response data (Dr. Hertz-Picciotto will note which effects could be quantified for the next draft)
 - ii. When this is not possible at least do a benchmark dose for the effect because it at least provides more information
- **5. Charge Question 3:** Should reduction/elimination of **exposure** be evaluated as a separate benefits category, in addition to or in conjunction with mortality and morbidity reduction?

The following comments and questions were raised in regard to Charge Question 3:

a. Dr. Hertz-Picciotto questioned that the exposure issue requires the public to be epidemiologists.

- b. Dr. Hanemann disagrees with the statements as written. It implies as a generalization that exposure never needs to be considered in regard to anxiety. For the arsenic case, it does not seem to be necessary to consider anxiety separate from benefits based on damage functions, but there are situations that can be envisioned where other social welfare metrics would be appropriate.
- c. Dr. Smith noted that we are in a middle ground here and that the economic analysis did adopt a damage function approach to link benefits to risk levels. It may be misleading to suggest another basis for evaluating benefits.
- d. Dr. Cropper noted that we could state that anxiety is a valid concern. To be estimated, anxiety wold need to be measurable with changes in exposure. However, the literature seems to suggest that exposure reductions need to be reduced to zero to remove anxiety for all.
- e. The section can be rewritten by deleting second and third paragraphs and rewriting paragraph one.
- f. The second paragraph on page 3 of the letter to the Administrator needs to be deleted to make the body and letter consistent based on these changes.
- **6.** Charge Question 4: How should total benefits and costs and incremental benefits and costs be addressed in analyzing regulatory alternatives to ensure appropriate consideration by decision makers and the public?

The following comments and questions were raised in regard to Charge Question 4:

- a. One member asked for clarification of whether EPA's benefits calculation recognized a benefit for the increment of exposure that in some systems that is above the current 50 ppb standard. The approach does not and this is intentional because of the need to assess the benefit associated with the current regulatory action alone. This is standard practice and for this rulemaking it would not be substantial at the national level.
- b. Another member noted the need to add a paragraph on policy implications for small systems due to low interest loan and grant availability.
- c. We should mention the traffic hazard risk increment as a possible omission that understates the costs if there is empirical evidence to support the Albuquerque comment.
- d. Mention the benefits associated with co-reduction of other contaminants.
- e. Check the OW comment about the citation regarding the proper elasticity figures. The Industrial Economics developed document has information on this. Dr. Freeman will check it.
- **7. Charge Question 5:** How should uncertainties be addressed in the analysis to ensure appropriate consideration by decision makers and the public?

The following comments and questions were raised in regard to Charge Question 5:

- a. The section in the document was written to focus on the concrete issues associated with arsenic.
- b. This is reasonable for the arsenic document; however, it might be helpful to add a couple of sentences at the beginning on why uncertainty analysis is important. The differences in the number of significant figures in the benefits and the costs sections was again noted as in need of emphasis. There is a generic tendency to understate uncertainty. Dr. Hattis will provide a paragraph on this.
- c. There is a need to link questions 1 and 5 in terms of the degree of uncertainty that exists in the latency issue. Also clarification of measurement error would be good. Dr. Hertz-Picciotto will provide wording for the revision.

8. General Comments on the Draft Letter to the Administrator

The following comments and questions were raised in regard to the General Comments Section:

- a. Dr. Bull noted his written comments on emphasis and tone. Dr. Cropper will incorporate this information.
- b. Discussion of question 2 could be stronger. It is possible to quantify some but extrapolation to low dose may require additional work.
- c. Define latency and cessation lag concept in the letter.
- d. Use the word 'estimate' instead of 'measure' in the letter.
- e. Check the wording on 'physical effects.'

9. Next Steps

- a. Schedule:
 - i) Dr. Cropper will revise the document and it will be sent to the Panel members and to the EC for concurrent review.
 - ii) SAB Executive Committee review of the Panel Report is to be on August 27
 - iii) Revisions and final report to the Administrator; Friday, August 31, 2001.

In closing Dr. Cropper thanked the Panelists.

12:00 pm Adjourn the Meeting

The Chair adjourned the meeting at 12:00 noon.

I certify that these minutes are accurate to the best of my knowledge.

/S/
Dr. Maureen Cropper
Chair
Arsenic Rule Benefits Review Panel

/S/

Mr. Thomas O. Miller
Designated Federal Officer
Arsenic Rule Benefits Review Panel

- Attachments:
 A Panel Review Draft of the Report to the Administrator, 8/9/01
 B FR 66(127), pp. 34924-34928, 7/2/01
 C Agenda

- D
- Panel Roster Log-in Sheets \mathbf{E}
- Public Comment by Dr. Craun for the City of Albuquerque \mathbf{F}

Attachment D

U.S. Environmental Protection Agency Science Advisory Board Executive Committee Arsenic Rule Benefits Review Panel*

CHAIR

Dr. Maureen L. Cropper, Lead Economist, The World Bank, Washington, DC Also Member: Advisory Council on Clean Air Compliance Analysis

OTHER SAB MEMBERS

Dr. Richard Bull, Consulting Toxicologist, MoBull Consulting, Kennewick, WA Member: Research Strategies Advisory Committee

Drinking Water Committee

Dr. W. Michael Hanemann, Professor, University of California, Berkeley, CA Member: Environmental Economics Advisory Committee

Dr. V. Kerry Smith, University Distinguished Professor, Department of Agricultural and Resource Economics, North Carolina State University, Raleigh, NC Member: Advisory Council on Clean Air Compliance Analysis

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